

4

Docket No. GJE-6035
Serial No. 09/913,814Remarks

Claims 1-14 were pending in the subject application. By this Amendment, claims 1, 9 and 11 have been amended, and claims 2, 3, 10, and 14 have been cancelled. Accordingly, claims 1, 4-9, and 11-13 are currently before the Examiner. The undersigned avers that no new matter is introduced by this amendment. Favorable consideration and entry of the amendments presented herein are respectfully requested.

The amendments and claim cancellations set forth herein should not be taken to indicate that the applicants have agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

Initially, the applicants respectfully request that the finality of the outstanding Office Action be withdrawn. The Office Action indicates that the applicants' amendments filed July 11, 2004 "necessitated" the new grounds of rejection and that, therefore, the Action has been made final. The applicants respectfully note that the amendment filed on July 11, 2004, simply involved taking the limitation of claim 10 and putting it into claim 1. Thus, the current rejection could have been made before and, therefore, should not now be made final.

The subject invention provides a unique composition in the form of a shaped body. The composition is freeze-dried, which provides an advantageous open matrix by removing solvent to leave the carbohydrate in space.

Claims 1, 4, 6, 7, 9, and 13 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,946,684 (Blank *et al.*). The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest the applicants' advantageous freeze-dried, open-matrix composition wherein the carbohydrate polymer is pullulan.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

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Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Please note that the rejection based on the Blank *et al.* reference was not applied to claim 3 and that the limitation of claim 3 has now been incorporated into claims 1 and 13 (and claim 3 has been canceled). Therefore, the applicants respectfully submit that this rejection does not now apply to claim 1 or 13. The rejection also does not apply to the claims which depend from claim 1 or which otherwise recite pullulan (such as claim 12). Reconsideration is respectfully requested.

Claims 1, 4, 6-9 and 13 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,010,719 (Remon *et al.*). The applicants respectfully traverse this ground for rejection because the Remon *et al.* reference does not disclose or suggest the applicants' advantageous freeze-dried, open-matrix composition wherein the carbohydrate polymer is pullulan.

Please note that this rejection was not applied to claim 3 and that the limitation of claim 3 has now been incorporated into claims 1 and 13 (and claim 3 has been canceled). Therefore, the applicants respectfully submit that this rejection does not now apply to claim 1 and the claims which depend therefrom or which otherwise recite pullulan. Reconsideration is respectfully requested.

Claims 3, 5 and 10-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over either of U.S. Patent No. 4,946,684 (Blank *et al.*) or U.S. Patent No. 6,010,719 (Remon *et al.*) as applied to claims 1, 2, 4, 6-9 and 13 and further in view of U.S. Patent No. 6,596,298 (Leung *et al.*). The applicants respectfully traverse this ground for rejection because the cited references, alone or in combination, do not disclose or suggest a composition, in the form of a shaped body, comprising a rapidly soluble open matrix of a carbohydrate polymer, wherein the carbohydrate polymer is pullulan.

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As noted above, neither Blank *et al.* nor Remon *et al.* disclose a rapidly soluble open matrix of a carbohydrate polymer wherein pullulan is the carbohydrate polymer. As discussed below, the cited art provides no motivation to modify the teachings of Blank *et al.* and/or Reman *et al.* to arrive at the advantageous composition of the present invention. Without such a motivation to modify the teachings of these references, a finding of obviousness is not proper.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, the references, even taken in combination, do not contain a suggestion to combine the secondary references with the primary references. It is only the applicants' disclosure that provides such a teaching, and the applicants' disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Spinnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The Office Action states that "Leung suggests that pullulan and other cellulose, starch or gum type film forming agents as equal in their efficiency to provide a rapid dissolving material to release active agents or medicaments." The applicants respectfully submit that this is not an entirely correct interpretation of the teachings of Leung *et al.*. Specifically, while the reference may cite these materials as being alternatives it does not disclose or suggest that they are equivalent. Leung *et al.* do not equate pullulan's efficacy with that of other film-forming agents.

As an analogy, please note that airplanes, cars, and trains are all alternatives for cross-country travel; however, these alternatives are by no means equivalent. Also, in contrast to choosing a method of transportation, where the best option may be readily apparent, here there is no clear rationale as to why one skilled in the art would select pullulan from this list of options and utilize it in an entirely different system for a different purpose.

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The Office Action goes on to say that "Leung teaches that pullulan is effective in delivering even lower doses of active agents ...", but does not explain where this teaching is or what it means in any context other than Leung's.

The applicants submit that it is not obvious to take pullulan from a film (as disclosed by Leung) and put it in an open matrix of the type described by Blank *et al.* or Remon *et al.* The purpose behind the Leung *et al.* invention, when using a therapeutic agent, is to provide a film *e.g.* to be kept in contact with the mucous membrane or open wound (see, for example, col. 3 lines 8-11). There is no reason to take a component from the Leung *et al.* system and put it in a quite different delivery vehicle.

Thus, the cited prior art makes no suggestion that pullulan is particularly suited to the preparation of useful open matrices as drug delivery systems. However, the Examples in the applicants' specification establish that the applicants' composition is, in fact, extremely effective and advantageous for this particular purpose.

The mere fact that the purported prior art could have been modified or applied in a manner to yield the applicants' invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art" *In re Dow Chemical Co.*, *supra* at 1531. In the references cited in support of the §103 rejection, one finds neither.

In summary, the applicants respectfully submit that the cited references do not provide any motivation for the skilled artisan to modify the cited references to arrive at the current invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

8

Docket No. GJE-6035
Serial No. 09/913,814

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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